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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,158	12/20/2001	Isabella Caniggia	11757.38USD1	4218

23552 7590 03/14/2003

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EXAMINER	
ANDRES, JANET L	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,158	CANIGGIA ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim(s) 1-5, drawn to methods of diagnosing conditions requiring regulation of trophoblast invasion comprising detecting TGF-beta 3 or its receptors, classified in class 424, subclass 9.34.

II. Claim(s) 1 and 2, drawn to methods of diagnosing conditions requiring regulation of trophoblast invasion comprising detecting HIF-1 alpha or oxygen tension, classified in class 424, subclass 9.1.

III. Claim(s) 1,2, and 6-13, drawn to methods of treating conditions involving trophoblast invasion by modulating TGF-beta 3 function, classified in class 424, subclass 158.1, and class 514, subclasses 2 and 44.

IV. Claim(s) 1, 6, and 11-13, drawn to methods of treating conditions involving trophoblast invasion by modulating HIF-1 alpha function, classified in class 514, subclass 2.

V. Claim(s) 14 and 15, drawn to a method of evaluating modulators of TGF-beta 3/receptor interaction, classified in class 435, subclass 7.1

VI. Claim(s)15, drawn to a method of evaluating modulators of TGF-beta 3/HIF-1 alpha interaction, classified in class 435, subclass 7.1

VII. Claim(s) 16-19, drawn to compositions affecting TGF-beta 3 function, classified in class 514, subclass 2.

VIII. Claim(s) 17 and 18, drawn to compositions affecting HIF-1 alpha function, classified in class 514, subclass 2.

Claims appear in more than one group if they encompass more than one invention.

The inventions are distinct, each from the other because of the following reasons:

The methods of Invention I are distinct from those of Invention II because they require different reagents.

The methods of Invention I are distinct from those of Invention III because they require different method steps and have different goals and outcome measures.

The methods of Invention I are distinct from those of Invention IV because they require different method steps and have different goals and outcome measures.

The methods of Invention I are distinct from those of Invention V because they require different method steps and have different goals and outcome measures.

The methods of Invention I are distinct from those of Invention VI because they require different method steps and have different goals and outcome measures.

The methods of Invention I are distinct from the compositions of Invention VII because they compositions have different uses, such as treatment.

The methods of Invention I are not related to the compositions of Invention VIII. The compositions cannot be used in the methods.

The methods of Invention II are distinct from the methods of Invention III because they require different method steps and have different goals and outcome measures.

The methods of Invention II are distinct from the methods of Invention IV because they require different method steps and have different goals and outcome measures.

The methods of Invention II are not related to the methods of Invention V. They require different method steps and different reagents and have different goals and outcome measures.

The methods of Invention II are not related to the methods of Invention VI. They require different method steps and different reagents and have different goals and outcome measures.

The methods of Invention II are not related to the compounds of Invention VII. The compounds cannot be used in the methods.

The methods of Invention II are distinct from the compositions of Invention VIII. The compositions have other uses, such as treatment.

The methods of Invention III are distinct from the methods of Invention IV because they require different reagents.

The methods of Invention III are distinct from the methods of Invention V because they require different method steps and different reagents and have different goals and outcome measures.

The methods of Invention III are distinct from those of Invention VI because they require different method steps and different reagents and have different goals and outcome measures.

The methods of Invention III are distinct from the compositions of Invention VII because the compounds have other uses, such as diagnosis.

The methods of Invention III are not related t o the compositions of Invention VIII because the compounds have other uses, such as diagnosis.

The methods of Invention IV are distinct from the methods of Invention V because they require different method steps and different reagents and have different goals and outcome measures.

The methods of Invention IV are distinct from the methods of Invention VI because they require different method steps and have different goals and outcome measures.

The methods of Invention IV are not related to the compositions of Invention VII. The compositions cannot be used in the methods.

The methods of Invention IV are distinct from the compositions of Invention VIII. The compositions have other uses, such as diagnosis.

The methods of Invention V are not related to the methods of Invention VI. They require different reagents and different method steps, and have different goals and outcome measures.

The methods of Invention V are distinct from the compositions of Invention VII because the compositions can be identified in other ways, such as by purification.

The methods of Invention V are not related to the compositions of Invention VIII. The compositions cannot be identified by the methods.

The methods of Invention VI are distinct from the compositions of Invention VII because the compositions can be identified in other ways, such as by purification.

The methods of Invention VI are distinct from the compositions of Invention VIII because the compositions can be identified in other ways, such as by purification.

The compositions of Invention VII are not related to the compositions of Invention VIII. They have different structures and different functions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the searches required for the different groups are different, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Antisense molecues

Protein inhibitors

These are different molecules with different structures and functions, and require different considerations. Success with one would not render success with another obvious.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 6, 7, 12, and 17 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly

signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
Patent Examiner

March 13, 2003